(2) Upon the effective date of registration of a product not currently registered.

§ 152.170 Criteria for restriction to use by certified applicators.

(a) *General criteria.* An end-use product will be restricted to use by certified applicators (or persons under their direct supervision) if the Agency determines that:

(1) Its toxicity exceeds one or more of the specific hazard criteria in paragraph (b) or (c) of this section, or evidence described in paragraph (d) of this section substantiates that the product or use poses a serious hazard that may be mitigated by restricting its use;

(2) Its labeling, when considered according to the factors in paragraph (e)(2) of this section, is not adequate to mitigate these hazard(s);

(3) Restriction of the product would decrease the risk of adverse effects; and

(4) The decrease in risks of the pesticide as a result of restriction would exceed the decrease in benefits.

(b) *Criteria for human hazard*—(1) *Residential and institutional uses.* A pesticide product intended for residential or institutional use will be considered for restricted use classification if:

(i) The pesticide, as diluted for use, has an acute oral LD_{50} of 1.5 g/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD_{50} of 2000 mg/kg or less;

(iii) The pesticide, as formulated, has an acute inhalation LC_{50} of 0.5 mg/liter or less, based upon a 4-hour exposure period;

(iv) The pesticide, as formulated, is corrosive to the eye (causes irreversible destruction of ocular tissue) or results in corneal involvement or irritation persisting for more than 7 days;

(v) The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe irritation (severe erythema or edema) at 72 hours; or

(vi) When used in accordance with label directions, or widespread and commonly recognized practice, the pesticide may cause significant subchronic, chronic or delayed toxic effects on man as a result of single or multiple exposures to the product ingredients or residues.

(2) *All other uses.* A pesticide product intended for uses other than residential or institutional use will be considered for restricted use classification if:

(i) The pesticide, as formulated, has an acute oral LD_{50} of 50 mg/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD_{50} of 200 mg/kg or less;

(iii) The pesticide, as diluted for use, has an acute dermal LD_{50} of 16 g/kg or less;

(iv) The pesticide, as formulated, has an acute inhalation LC_{50} of 0.05 mg/liter or less, based upon a 4-hour exposure period;

(v) The pesticide, as formulated, is corrosive to the eye or causes corneal involvement or irritation persisting for more than 21 days;

(vi) The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring); or

(vii) When used in accordance with label directions, or widespread and commonly recognized practice, the pesticide may cause significant subchronic toxicity, chronic toxicity, or delayed toxic effects on man, as a result of single or multiple exposures to the product ingredients or residues.

(c) *Criteria for hazard to non-target species*—(1) *All products.* A pesticide product intended for outdoor use will be considered for restricted use classification if:

(i) When used according to label directions, application results in residues of the pesticide, its metabolites, or its degradation products, in the diet of exposed mammalian wildlife, immediately after application, such that:

(A) The level of such residues equals or exceeds one-fifth of the acute dietary LC_{50}; or

(B) The amount of pesticide consumed in one feeding day (mg/kg/day) equals or exceeds one-fifth of the mammalian acute oral LD_{50};

(ii) When used according to label directions, application results, immediately after application, in residues of the pesticide, its metabolites or its

degradation products, in the diet of exposed birds at levels that equal or exceed one-fifth of the avian subacute dietary LC_{50};

(iii) When used according to label directions, application results in residues of the pesticide, its metabolites or its degradation products, in water that equal or exceed one-tenth of the acute LC_{50} for non-target aquatic organisms likely to be exposed; or

(iv) Under conditions of label use or widespread and commonly recognized practice, the pesticide may cause discernible adverse effects on non-target organisms, such as significant mortality or effects on the physiology, growth, population levels or reproduction rates of such organisms, resulting from direct or indirect exposure to the pesticide, its metabolites or its degradation products.

(2) *Granular products.* In addition to the criteria of paragraph (c)(1) of this section, a pesticide intended for outdoor use and formulated as a granular product will be considered for restricted use classification if:

(i) The formulated product has an acute avian or mammalian oral LD_{50} of 50 mg/kg or less as determined by extrapolation from tests conducted with technical material or directly with the formulated product; and

(ii) It is intended to be applied in such a manner that significant exposure to birds or mammals may occur.

(d) *Other evidence.* The Agency may also consider evidence such as field studies, use history, accident data, monitoring data, or other pertinent evidence in deciding whether the product or use may pose a serious hazard to man or the environment that can reasonably be mitigated by restricted use classification.

(e) *Alternative labeling language.* (1) If the Agency determines that a product meets one or more of the criteria of paragraphs (b) or (c) of this section, or if other evidence identified in paragraph (d) of this section leads the Agency to conclude that the product should be considered for restricted use classification, the Agency will then determine if additional labeling language would be adequate to mitigate the identified hazard(s) without restricted use classification. If the labeling language meets all the criteria specified in paragraph (e)(2) of this section, the product will not be classified for restricted use.

(2) The labeling will be judged adequate if it meets all the following criteria:

(i) The user, in order to follow label directions, would not be required to perform complex operations or procedures requiring specialized training and/or experience.

(ii) The label directions do not call for specialized apparatus, protective equipment, or materials that reasonably would not be available to the general public.

(iii) Failure to follow label directions in a minor way would result in few or no significant adverse effects.

(iv) Following directions for use would result in few or no significant adverse effects of a delayed or indirect nature through bioaccumulation, persistence, or pesticide movement from the original application site.

(v) Widespread and commonly recognized practices of use would not nullify or detract from label directions such that unreasonable adverse effects on the environment might occur.

§ 152.171 Restrictions other than those relating to use by certified applicators.

The Agency may by regulation impose restrictions on a product or class of products if it determines that:

(a) Without such restrictions, the product when used in accordance with warnings, cautions and directions for use or in accordance with widespread and commonly recognized practices of use may cause unreasonable adverse effects on the environment; and

(b) The decrease in risks as a result of restricted use would exceed the decrease in benefits as a result of restricted use.